Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA INT'L FEDERAL EXPRESS

June 8, 2001

Our Reference: 2956450

William A. Weiner, President
WAW Enterprises
1052 Cabras Highway
Guam United Warehouse
Piti, Guam 96925

WARNING LETTER

Dear Mr. Weiner:

On April 11 and 15, 2001, we inspected your seafood firm to determine your compliance with FDA's Seafood HACCP regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deviations. These deviations cause your tuna and marlin to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the deficiencies on a Form FDA 483 (Inspectional Observations) and discussed them with you at the conclusion of the inspection. The deviations are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan to control the food safety hazard of histamine formation as a result of time/temperature abuse in chilled tuna and marlin received directly from the harvest vessel.

2. You must adequately monitor and document sanitation conditions and practices, to comply with 21 CFR 123.11(b) and (c). However, your firm did not monitor and maintain records related to the following areas of sanitation to ensure control:

a) Safety of water;
b) Condition and cleanliness of food contact surfaces;
c) Prevention of cross-contamination;
d) Maintenance of hand washing, hand sanitizing, and toilet facilities;
e) Protection of food and food contact surfaces from adulterants;
f) Proper labeling and storage of toxic compounds;
g) Control of employee health conditions; and
h) Exclusion of pests from the processing area.

We may take further regulatory action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response documentation such as time/temperature monitoring records, sanitation records, HACCP plans, etc. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your seafood firm operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Darrell T. Lee
Acting Director
San Francisco District